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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,658	12/05/2003	Istvan Szelenyi	6319-1815	8943
29858 7590 06/13/2007 THELEN REID BROWN RAYSMAN & STEINER LLP 900 THIRD AVENUE NEW YORK, NY 10022			EXAMINER KWON, BRIAN YONG S	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 06/13/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/727,658

Applicant(s)

SZELENYI ET AL.

Examiner

Brian S. Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-30 is/are pending in the application.
- 4a) Of the above claim(s) 17-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-16 and 25-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/19/07</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Acknowledgment is made of applicant's filing of an amendment filed 03/19//2007. By the amendment, claims 13-14, 16 and 26 have been amended and claims 27-30 have been newly added.
2. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 13, 14 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is essentially analogous to the previous rejection mailed 12/15/2006.

Regarding claims 13, 14 and 28, the claims recite "other tolperisone analogs". It is not clear what "other tolperisone analogs" refers to. The specification does not define the term and leaves the reader in doubt as to the meaning of the invention to which they refer, thereby rendering the definition of the subject-matter of said claims unclear.

Furthermore, since the breadth of "other tolperisone analogs" encompasses "eperisone, silperisone", the applicant's recitation of "other tolperisone analogs" along with "eperisone,

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silperisone” makes claim redundant. Consequently, this redundancy of the claims renders the definition of the subject-matter of said claims unclear.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 13, 15 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lobisch et al. (US 5162346) in view of Cai et al. (US 6281211).

Lobisch teaches the use of flupirtine for the treatment of neuralgia (or neuropathic pain), wherein said compound is administered in various dosage forms including oral or parenteral forms (column 2, line 67; column 3, lines 9-18; column 6, lines 42-43; and claim 2).

Cai is being supplied as reference to demonstrate the routine knowledge in using Na<sup>+</sup> channel blocker such as riluzole, lidocaine, propagenone and semicarbazone derivatives for the treatment neuropathic pain (see particularly "Related Background Art" in column 1, lines 18-56 and "Summary of Actions"; abstract).

The teaching of Lobisch differs from the claimed invention in the combination use of flupirtine and sodium channel blocker such as lidocaine, propagenone and riluzole for the treatment of neuralgia or neuropathic pain. To incorporate such teaching into the teaching of Lobisch, would have been obvious in view of Cai who teaches the use of sodium channel blocker such as riluzol, lidocaine and propagenone for the treatment of neuralgia or neuropathic pain.

Above references in combination make clear that flupirtine and sodium channel blockers such as lidocaine, propageneone and riluzole have been individually used for the treatment of neuralgia or neuropathic pain. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. *See In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

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With respect to the determination of various dosage forms (e.g., orally, rectally, intravenously, transdermally, subcutaneously or intracutaneously) and the current administration regimen of two drugs (e.g., simultaneously, separately or consecutively), such determination of appropriate dosage forms and administration regiment for treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of drug delivery information provided in the prior art references.

5. Claims 14, 16 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lobisch et al. (US 5162346) in view of Cai et al. (US 6281211), and further in view of the applicant's admitted prior art of record (page 3, lines 11-23).

The modified teaching of Lobisch (Lobisch in combination with Cai) includes all that is recited in the claims 15 and 16 except the use of "tolperisone, eprisone and silperisone".

The admitted prior art of record teaches tolperisone as sodium channel blocker similar to lidocaine.

One having ordinary skill in the art would have expected that tolperisone would behave similar as to the known sodium channel blocker such as lidocaine and provide therapeutic utility in the treatment of neuralgia or neuropathic pain through sodium channel blocking mechanism. One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

***Response to Arguments***

6. Applicant's arguments filed 03/19/07 have been fully considered but they are not persuasive.

Applicant's argument in the response takes the position that it is readily apparent to one of skill in the art what the term "tolperisone analogs" refers to, for example in light of the submitted USP 4181803 and USP 4528299.

This argument is not found persuasive. Unlike the applicant's argument, the instant specification does not clear define the term, nor provides any examples of "other tolperisone analogs" other than eperisone and silperisone. Especially, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompasses a myriad of possibilities, the skill artisan should doubt as to the meaning of the invention to which they refer, thereby rendering the definition of the subject-matter of said claims unclear.

Furthermore, as discussed above, the applicant's recitation of "other tolperisone analogs" along with "eperisone, silperisone" in the claims makes claim redundant since the breadth of "other tolperisone analogs" encompasses "eperisone, silperisone". Consequently, this redundancy of the claims renders the definition of the subject-matter of said claims unclear.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5

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USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, the prior art references in combination (Lobisch and Cai) make clear that flupirtine and sodium channel blocker such as lidocaine, propageneone and riluzole have been individually used for the treatment of neuralgia or neuropathic pain. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. *See In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

### Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. No Claim is allowed.

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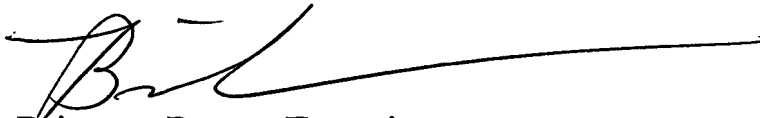
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon

A handwritten signature in black ink, appearing to be 'Brian Kwon', with a long horizontal stroke extending to the right.

Primary Patent Examiner

AU 1614